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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,805	03/18/2004	Gennady V. Merkulov	CL001186DIV-II	6122

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EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)
	10/802,805	MERKULOV ET AL.
	Examiner	Art Unit
	Chun Crowder	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 24-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/18/04, 09/30/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of this application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Chun Crowder, Group Art Unit 1644, Technology Center 1600.

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

3. Applicant's amendment to the claims, filed 09/25/2006, is acknowledged. Because of the cancellation of claims 1, 2, and 4-23, the Restriction Requirement, mailed 08/24/2006, is rendered moot.

Claims 1, 2, and 4-23 have been canceled.
Claims 24-36 have been added.

Claims 3 and 24-36 are pending and currently under consideration as they read on an isolated antibody that selectively binds to a polypeptide of SEQ ID NO:2.

4. Applicant's claim for domestic priority is acknowledged. The priority applications USSNs 09/820,001 and 10/003,302 upon which benefit is claimed appear to provide adequate support under 35 U.S.C. 112 for subject matter claimed in the instant application.

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 121 and 365(c), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

The specification on page 1, line one should be amended to reflect the status of the priority applications USSNs 09/820,001 and 10/003,302 which are now US Patent 6,387,680 and 6,867,030, respectively.

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

6. Applicant's IDSs, filed 06/18/2004 and 09/30/2005, are acknowledged and have been considered.

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (e.g. line 13 on page 11 of the instant specification). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

In addition, the application is required to be reviewed and all spelling, TRADEMARK, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent application, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27-30 are indefinite in the recitation of "wherein the antibody is coupled to a detectable substance." There is insufficient antecedent basis for this limitation in this claim. The base claims from which the rejected claims depend recite "an isolated antibody", not an antibody coupled to a detectable substance.

Applicant is suggested to amend the rejected claims to an independent claim which recites "an antibody coupled to a detectable substance" in the preamble, and then recite the elements of the conjugate.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 3, 24-26, and 31-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Xiao (WO 02/36754. Reference on IDS, filed 06/18/2004) (see entire document) as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886) and the instant specification (page 23 of the instant specification).

Xiao teaches a lysosomal acid lipase polypeptide having amino acid sequence of SEQ ID NO:5 that is 95% identical to the claimed SEQ ID NO:2 (see entire document, particularly Figure 5 and claim 1). Further, Xiao teaches that the lysosomal acid lipase polypeptide and its fragments can be used to make antibodies including monoclonal antibodies, antigen-binding fragments such as Fab, $F(ab')_2$ and Fv; these antibodies in a composition can be used therapeutically as well as in immunoassays such as ELISA (e.g. see Antibodies on pages 29-32).

As evidenced by Bost et al, antibodies can be specific and cross-react with the antigen. For example, antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document; but especially the Abstract and Discussion). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (e.g., see Results, page 579).

As further evidenced by Bendayan, the specific reactivity of a monoclonal antibody can be highly specific yet cross-react with antigens from different species or even distinct proteins not related to the original antigen (page 886, last paragraph).

Furthermore, the instant specification discloses that an antibody is still considered to selectively bind a peptide even if it also binds to other proteins that are not substantially homologous with the target peptide so long as such proteins share homology with a fragment or domain of the peptide target of the antibody; antibody binding to the peptide is still selective despite some degree of cross-reactivity.

Consequently, it was well known in the art at the time the invention was made that antibody binding of distinct proteins was indeed specific. Therefore, the reference antibody to SEQ ID NO:5 is specific to proteins with the instant claimed polypeptide comprising/consisting of SEQ ID NO:2.

Therefore, the reference teachings anticipate the claimed invention.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 3, 24-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao (WO 02/36754. Reference on IDS, filed 06/18/2004) in view of Bost et al. (Immunol. Invest. 1988; 17:577-586), Bendayan (J. Histochem. Cytochem. 1995; 43:881-886), the instant specification (page 23 of the instant specification), and Harlow et al. (Antibodies. A Laboratory Manual. 1988. pages 319, 321-339).

The teachings of Xiao, Bost et al, Bost, and the instant specification have been discussed, supra.

The reference teachings differ from the claimed invention by not describing an antibody that is coupled to a detectable substance and an antibody composition.

However, the methods of coupling antibody to a detectable substance and methods of using coupled antibody and antibody composition were well know in the art at the time the invention was made. For example, Harlow et al. teach that a wide range of immunological techniques depend on the use of labeled antibodies such as fluorescent labels because directly labeled antibodies involves fewer steps and are less prone to background problems; and Harlow et al. teach antibodies composition in well known carriers (see entire document, particularly pages 321-326).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce antibody selectively binds to the claimed SEQ ID NO:2 and couple the antibody to a detectable labels and to use antibody composition in well known carriers. The ordinary artisan would have been motivated to do so because antibody coupled to detectable substance can be used in a wide range of immunological techniques.

Given the teachings of Xiao, Bost et al, Bendayan, and the instant specification regarding methods of making monoclonal antibody to a lysosomal acid lipase polypeptide that is 95% identical the instant SEQ ID NO:2, and the teachings of Harlow et al. providing the method and advantages of making and using antibody coupled with detectable labels, the ordinary artisan at the time the invention was made would have had a reasonable expectation of success of producing the claimed antibody that is coupled to a detectable substance.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chun Crowder, Ph.D.
Patent Examiner
December 21, 2006

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PRIMARY EXAMINER
TC 1600
12/12/06